EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Stakeholders engagement

The EU medicines regulatory system and the European Medicines Agency: an introduction for international regulators and non-governmental organisations

18-19 September 2017

Presented by Maria Mavris and Marie-Helene Pinheiro, on 19 September 2017
Stakeholders and Communication Department

EMA Stakeholder engagement principles

Context, background and objectives
Principles and Frameworks

EMA and its Stakeholders

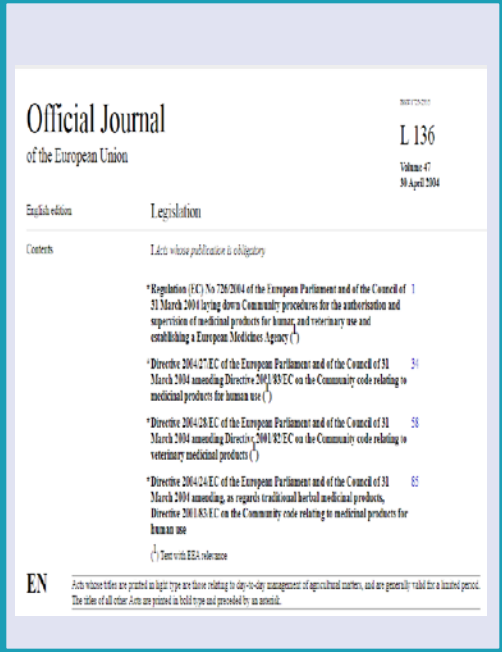
EUROPEAN MEDICINES AGENCY

An interaction foreseen by EU Legislation

Article 78

1. The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and the representatives of the industry, consumers and patients and the health professions. These contacts may include the participation of observers in certain aspects of the Agency's work, under conditions determined beforehand by the Management Board, in agreement with the Commission.

2. The committees referred to in Article 56(1) and any working parties and scientific advisory groups established in accordance with that Article shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organisations and health-care professionals' associations. Rapporteurs appointed by these committees may, on an advisory basis,



Official Journal
of the European Union

L 136
Volume 47
30 April 2004

English edition

Legislation

Contents

I *Acts whose publication is obligatory*

* Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (*) 1

* Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (*) 34

* Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (*) 58

* Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use 85

(*) Text with EEA relevance

EN

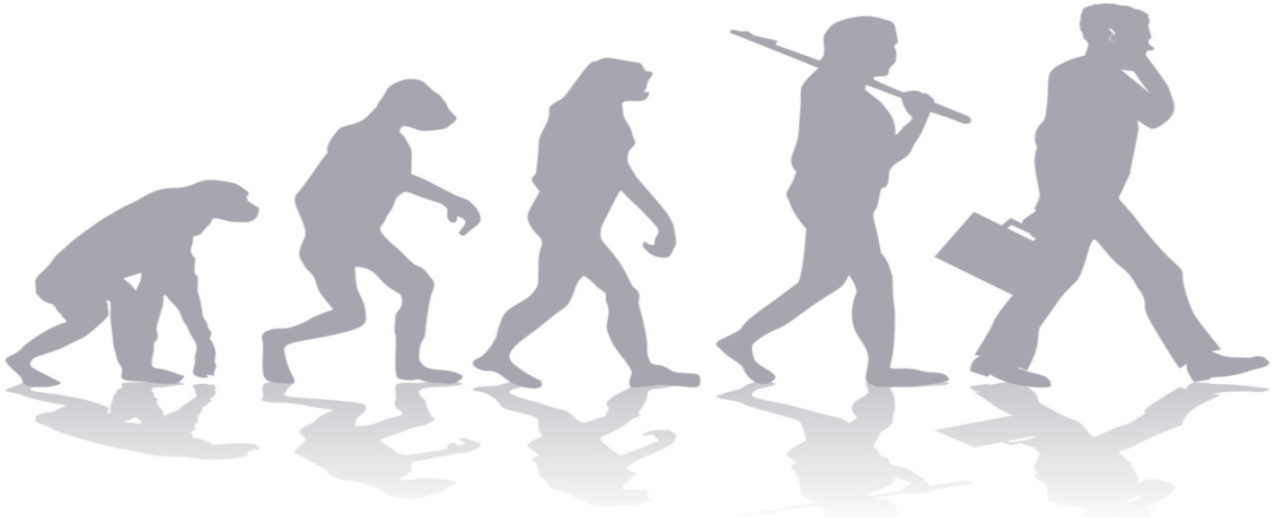
Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period. The titles of all other Acts are printed in bold type and preceded by an asterisk.

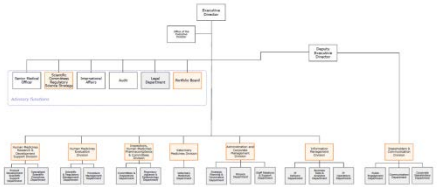
EMA and its Stakeholders

EUROPEAN MEDICINES AGENCY

The EMA has been interacting with its stakeholders on various levels since its creation.

A natural evolution…





Need for common principles, better coordination and streamlining?

EMA and its stakeholders over the years

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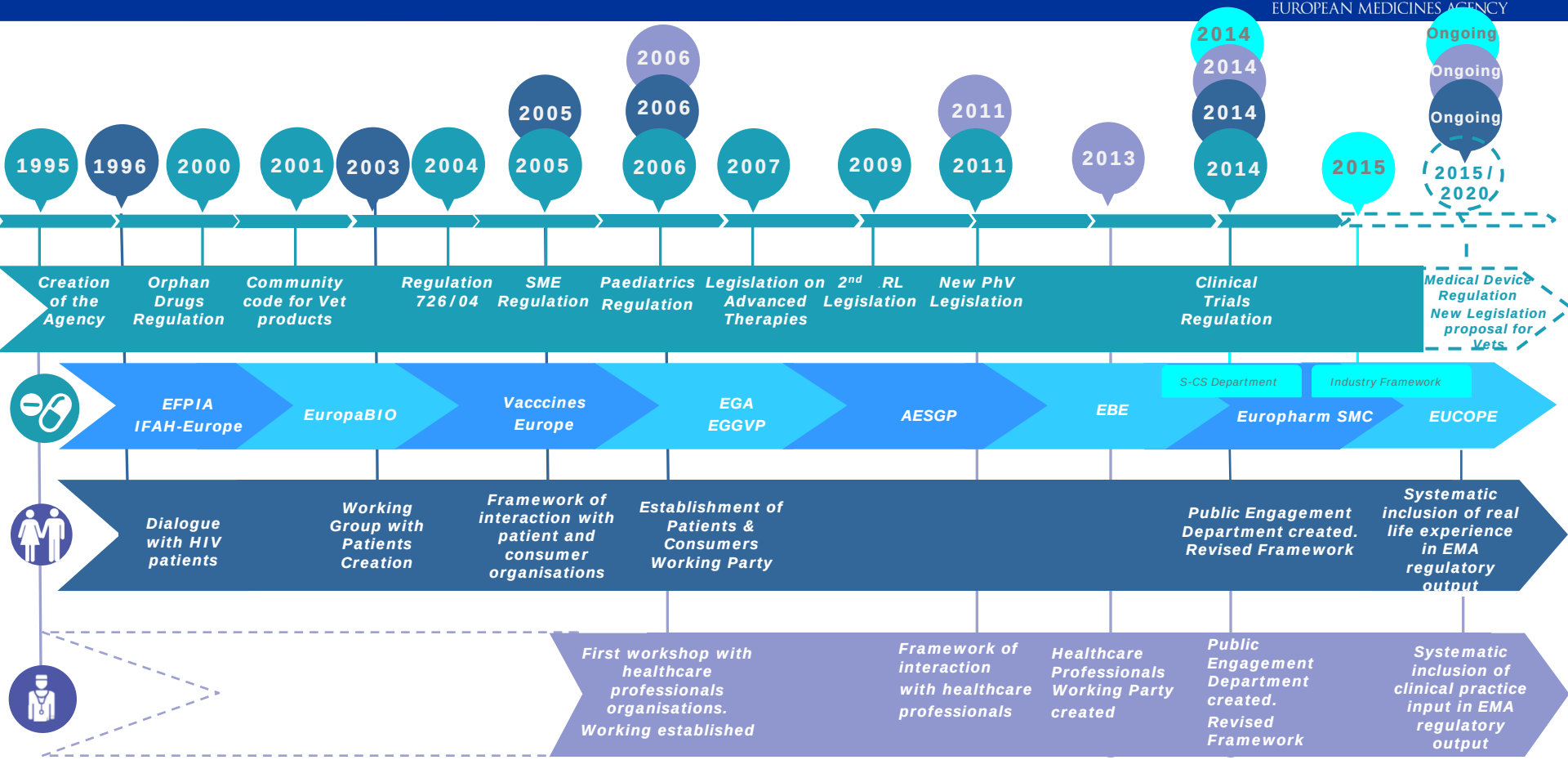

EMA Stakeholder engagement principles

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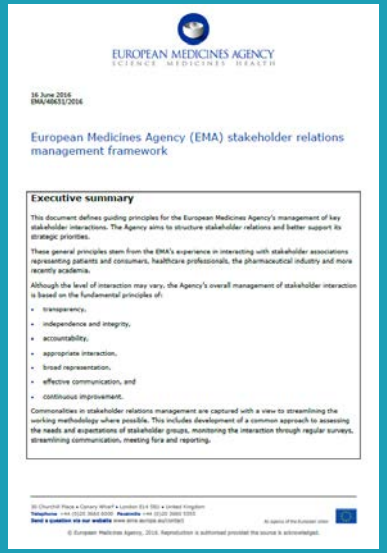
Stakeholder interaction must be based on the fundamental principles:

- *Transparency*
- *Independence and integrity*
- *Accountability*
- *Appropriate interaction*
- *Broad representation*
- *Effective communication*
- *Continuous improvement*

EMA Stakeholder Relation Management Framework

June 2016



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16 June 2016
EMA/40651/2016

European Medicines Agency (EMA) stakeholder relations management framework

Executive summary

This document defines guiding principles for the European Medicines Agency's management of key stakeholder interactions. The Agency aims to structure stakeholder relations and better support its strategic priorities.

These general principles stem from the EMA's experience in interacting with stakeholder associations representing patients and consumers, healthcare professionals, the pharmaceutical industry and more recently academia.

Although the level of interaction may vary, the Agency's overall management of stakeholder interaction is based on the fundamental principles of:

- transparency,
- independence and integrity,
- accountability,
- appropriate interaction,
- broad representation,
- effective communication, and
- continuous improvement.

Commonalities in stakeholder relations management are captured with a view to streamlining the working methodology where possible. This includes development of a common approach to assessing the needs and expectations of stakeholder groups, monitoring the interaction through regular surveys, streamlining communication, meeting fora and reporting.

EMA Stakeholder engagement principles

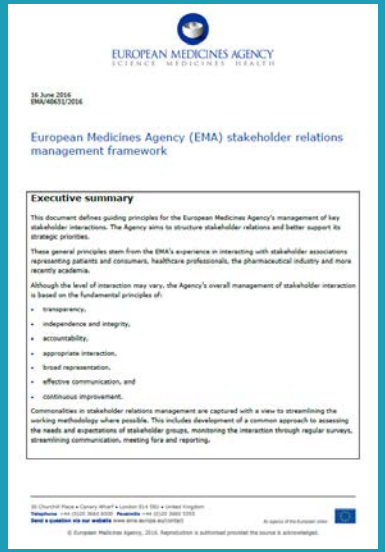
EUROPEAN MEDICINES AGENCY

Agency aims to:

- *Promote appropriate engagement and dialogue;*
- *Provide efficient, targeted and timely information, in a proactive manner;*
- *Enhance stakeholders' understanding of the EU medicines Regulatory network and enrich EMA's understanding of issues that are pertinent from the stakeholders' perspective;*
- *Increase transparency on how EMA engages with stakeholders;*
- *Structure stakeholder relations and better support EMA's strategic priorities.*

EMA Stakeholder Relation Management Framework

June 2016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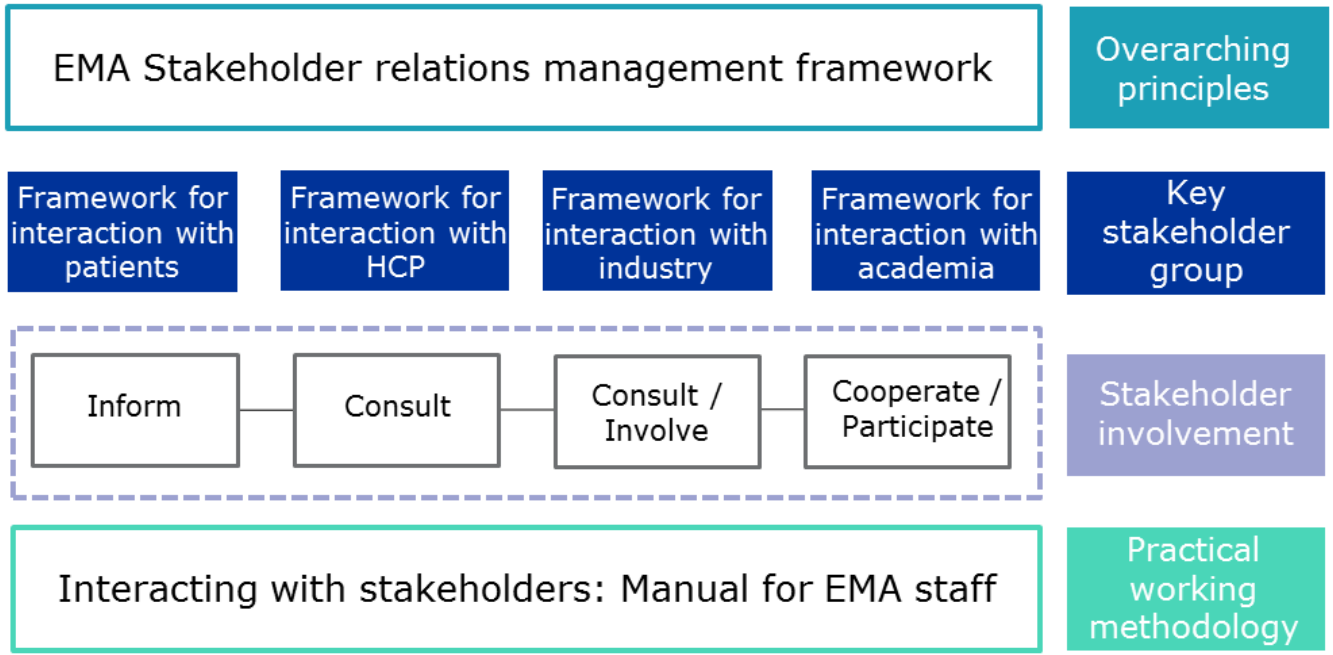

Together, these building blocks ensure a **consistent approach to stakeholder relations management** across a variety of stakeholder groups and interaction types.

EMA and its Stakeholders working methodology

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INFORM

e.g. announcement of review of policy or guidance; info Days

CONSULT

Written – e.g. public consultation on policies or guidance, surveys

CONSULT & INVOLVE

direct interactions – e.g. meetings, workshops, public hearings

COOPERATE / PARTICIPATE

direct interactions - e.g. technical expert groups (Telematics, ENCePP) technical expert groups

Based on EC Better Regulation Guidelines

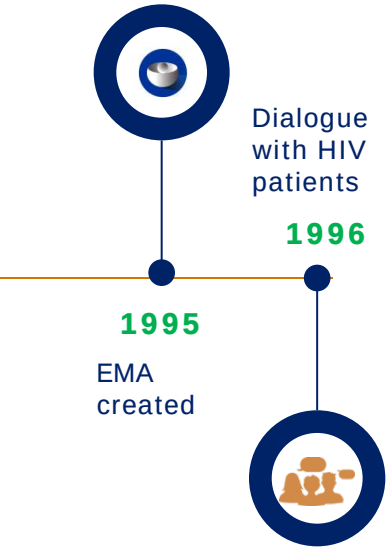
EMA Stakeholder engagement

Interactions with stakeholder groups

EMA Stakeholder engagement

*EMA and **patients and consumers***

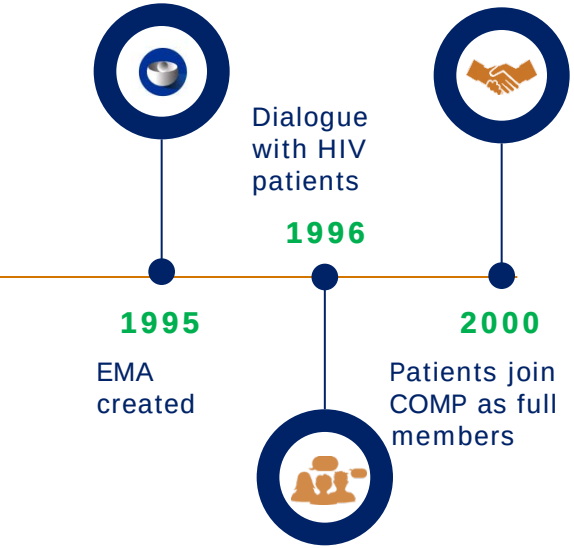
In the beginning…

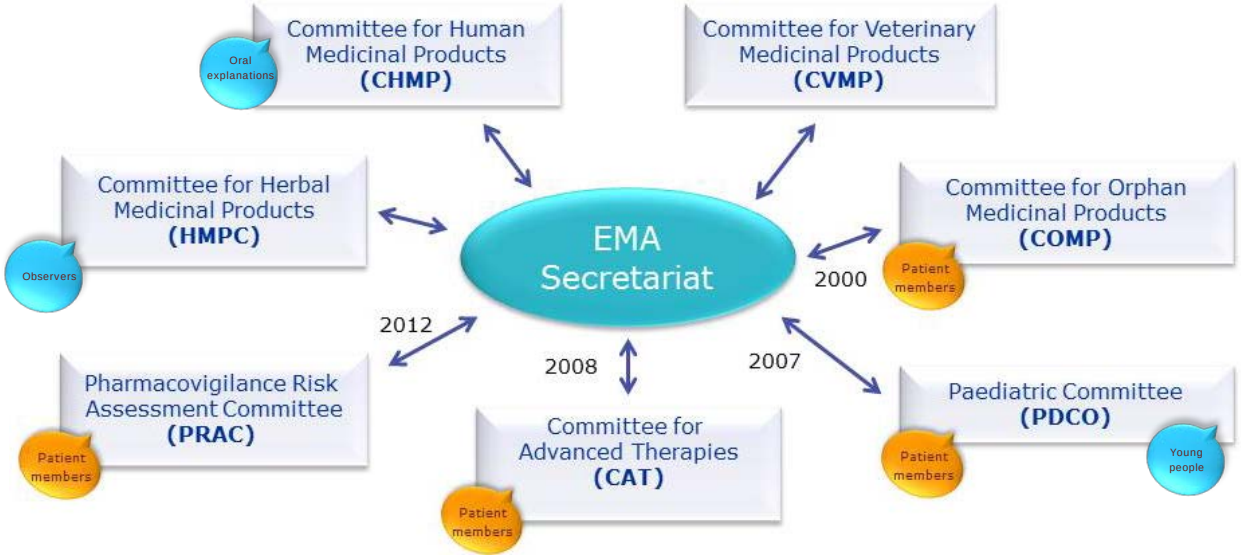


1996
Building the foundation of the interaction between EMA and patients

- *EMA Management Board signalled of the danger of neglecting partnership with stakeholders, public, healthcare professions and pharmaceutical industry*
- *EMA started dialogue with HIV patients on the value of surrogate markers in the approval of anti HIV drugs leading to the early approval of protease inhibitors*

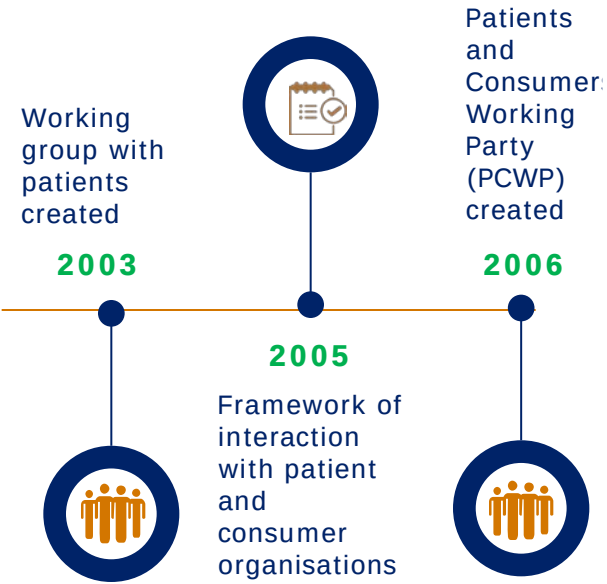
Five years later…





Patients, Healthcare Professionals and Academia at EMA

Framework and working party



Patients' and Consumers' Working Party (PCWP)

Patients, Healthcare Professionals and Academia at EMA

The continuing story….

1995
EMA created

1996
Dialogue with HIV patients

2000
Patients join COMP as full members

2003
Working group with patients created

2005
Framework of interaction with patient and consumer organisations

2006
Patients and Consumers Working Party (PCWP) created

2014
Dedicated Department created & framework updated

2017
Systematic inclusion of real life experience EMA regulatory output

Ongoing…
Public Hearing

EMA Stakeholder engagement

*EMA and **Healthcare professionals***

Healthcare professionals and EMA

*EMA recognised the importance of **bridging** the regulatory and real-life clinical practice worlds.*

Healthcare professionals are part of:

- *Management Board*
- *Scientific committees*
- *Working parties*
- *Expert groups*
- *Also as individual experts*

Healthcare Professionals' Working Party (HCPWP)

Healthcare professionals – who are they?

- *General practitioners and family physicians*
- *Hospital pharmacists*
- *Pharmaceutical group*
- *Nurses (specialised or general)*
- *Specialists (e.g. diabetes, oncology, epilepsy, geriatrics, paediatrics…)*

Framework

The framework aims to:

- *Support access to best possible **independent expertise** in clinical practice,*
- *Contribute to a more efficient and targeted **communication** to healthcare professionals,*
- *Enhance **understanding** of the role and activities of the EU medicines Regulatory Network.*

Recognises:

- *Importance of involving healthcare professionals in the field of **clinical practice** foresees the establishment of pools of experts*
- *Need to stimulate areas of shared interest with **academia***
- *Further strengthen the established **collaboration** with patient and consumer organisations*

Framework of interaction with healthcare professionals

Action plan

EMA Stakeholder engagement

*EMA and **academia***

EMA and academia

- *There has always been an interaction between academia and regulators*
- *No direct mention of academia in regulations - many references to regulatory decisions based on **scientific evidence***

- *Framework created supporting **interaction and dialogue** between EMA, academia and broader EU scientific communities*
- *Revised healthcare professionals framework focused primarily on clinical practice*
- *Academia framework focuses on **research and education***
- *Common objectives shared in both frameworks*

Academics and researchers and the EMA

Framework of collaboration with academia

Action plan

The framework objectives are:

- *Raise **awareness** of the work of the European medicines regulatory network*
- *Promote and further develop the **regulatory support** to academic research*
- *Support timely and effective evidence generation, regulatory **advice and guidance***
- *Work in **collaboration** with the regulatory network in developing regulatory science*

Academia pages on EMA website

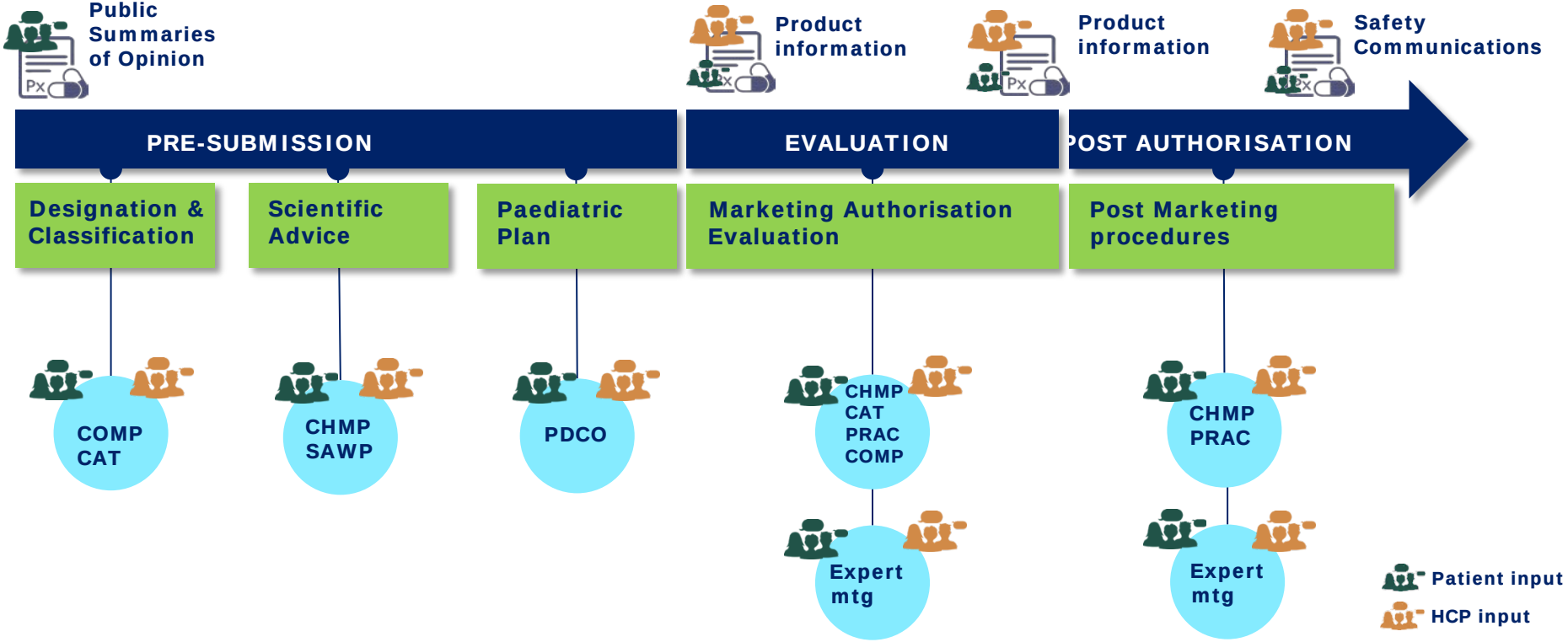
EMA Stakeholder engagement

Patients and consumers** and **healthcare professionals level of engagement

Patients and consumers and healthcare professionals Representation within EMA

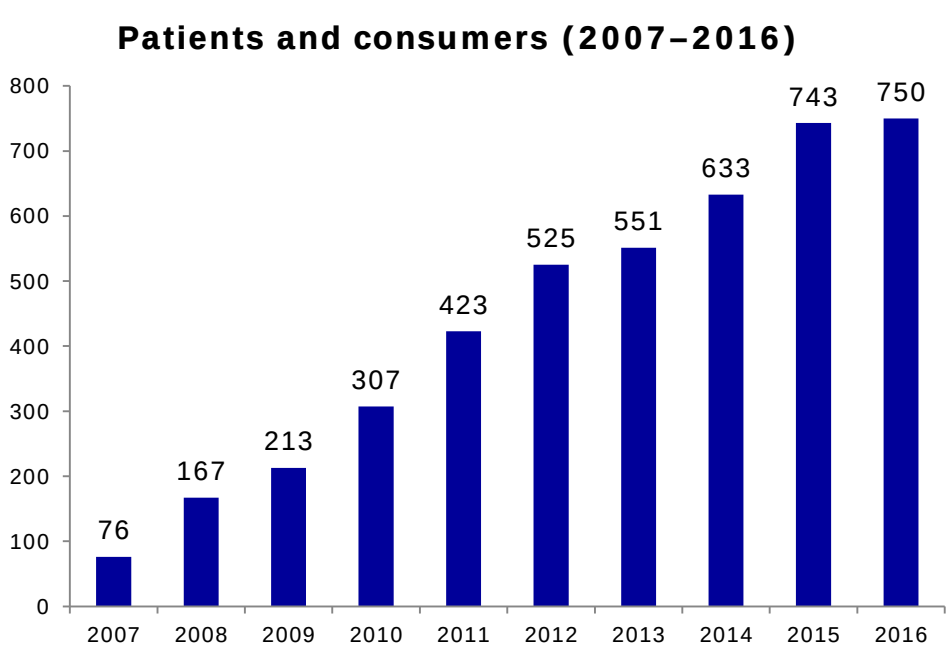
Representing their *community*	•*Management Board* •*EMA Scientific Committee Members*
Representing their *organisations*	•*Working Party (PCWP or HCPWP)* •*EMA consultations* •*Workshops*
Individual experts	•*Scientific Advice / Protocol Assistance Procedures* •*Scientific Advisory/ad hoc expert Groups* •*Scientific Committee consultations* •*Review of documents*

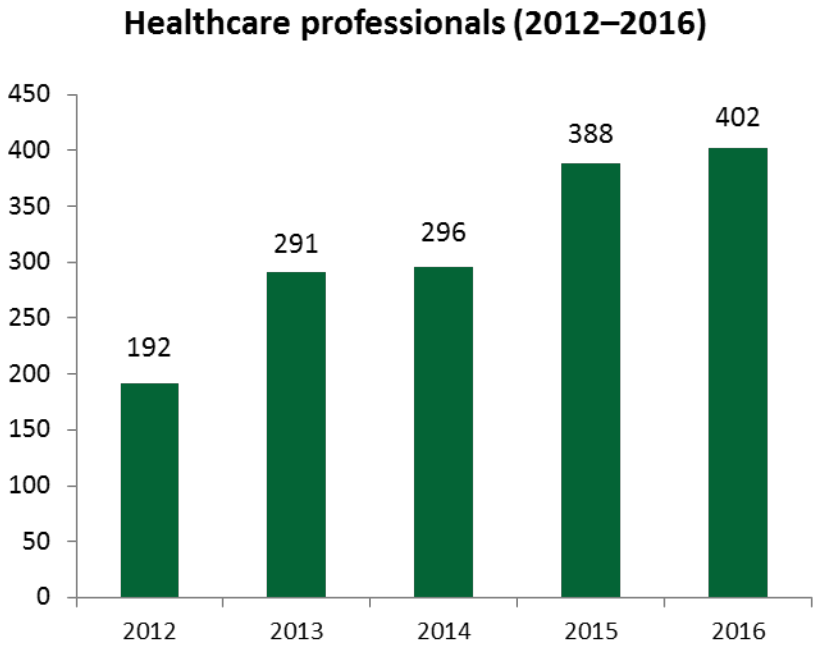
Involvement along the medicine lifecycle at EMA



Patients, Healthcare Professionals and Academia at EMA

Increasing involvement in EMA activities





Patients, Healthcare Professionals and Academia at EMA

EMA Stakeholder engagement

Patients and consumers, healthcare professionals and academia lessons learnt

Challenges for patients

- *Identify when regulators should get views from **individual** patients versus the patient **community***
- *Research how to **collect and use** the wealth of information*
- *Measuring the **value / impact** of patients*
- *Identify and address all legal, regulatory, financial **issues** that could give rise to procedural barriers to patients' involvement*

- ***Finding patients** (e.g. language barrier, availability, disease area) - managing potential conflicts of interest*
- *Ensuring comprehensive, tailored **training** to facilitate and enhance participation*

Challenges for healthcare professionals

- *Maintaining **interest** and levels of **participation** in EMA activities*
- *Ensuring consistency in provision of **feedback***
- *Providing **contextualised information** of EMA activities*
- *Striking the **right balance** between clinical practice and academic/research interests*
- *Expanding **outreach***
- *Research how to **collect and use** the wealth of information available from healthcare professionals in post-marketing phase*

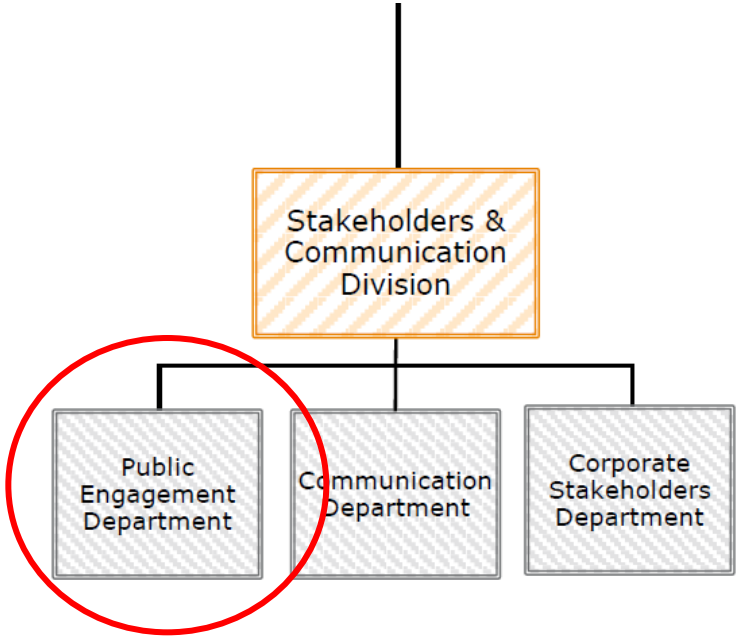
Challenges for academia

- *Building of an effective **working model** for enhancing and fostering collaboration*
- *Creation of a **space of convergence** that would allow for changes in the modus operandi on both sides while balancing between the constraints of regulation and the free breathing space of research and innovation.*
- *Capacity and financial **resources** represent a major challenge for academics*
- ***Communication and engagement** are key areas*

How to address the challenges

- ***Who*** *to interact with?*
  - *Creating a diverse group of stakeholders to consult*
  - *Criteria for organisations*
  - *Individual experts*
- ***How*** *to interact?*
  - *Methodologies for engaging stakeholders*
  - *Support and training*
  - *Develop appropriate content and ensure targeted communication*
- ***Transparency***
- ***Monitoring*** *and* ***reporting***

Creation of a dedicated department



Who do we work with?

*Through a **network of eligible organisations** fulfilling the following **criteria**:*

- *Legitimacy*
- *Mission/activities*
- *Representation*
- *Structure*
- *Accountability*
- *Transparency*

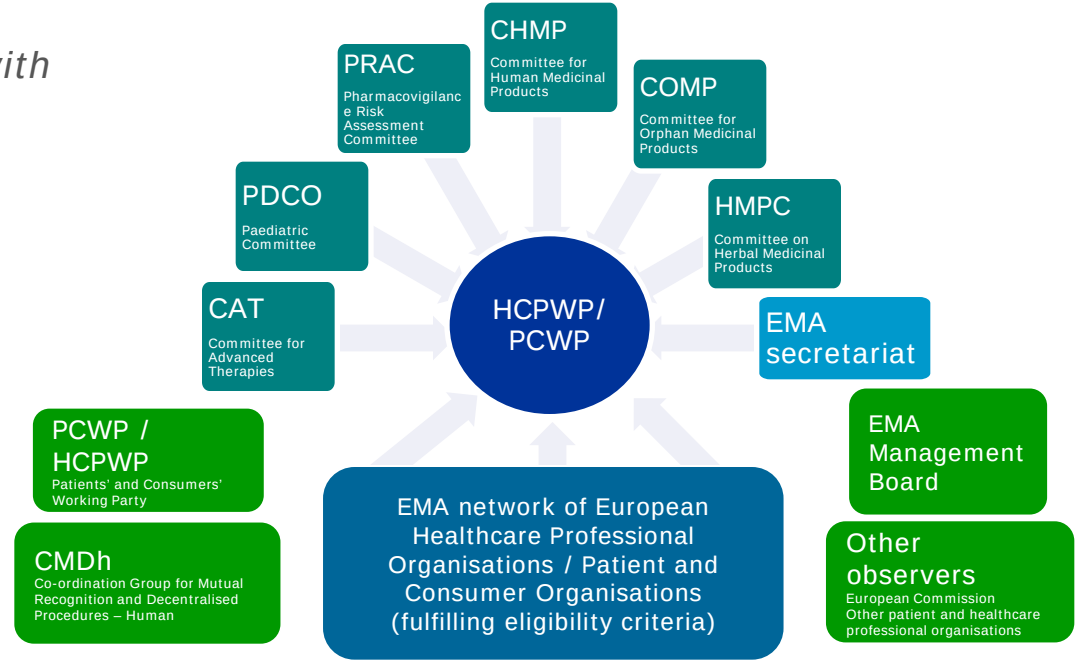
Representatives	Experts
Consulted on issues of general interest (e.g. Policies, guidelines, clinical trial register)	Consulted on issues related to evaluation of medicines
Present the position of the organisation they represent	Provide their own experience/ expertise on the disease and its management
Involved in non-confidential discussions	Sign a confidentiality undertaking
Transparent on the funding of the organisations	**Fill in declaration of interest**

Patients' and consumers' organisations

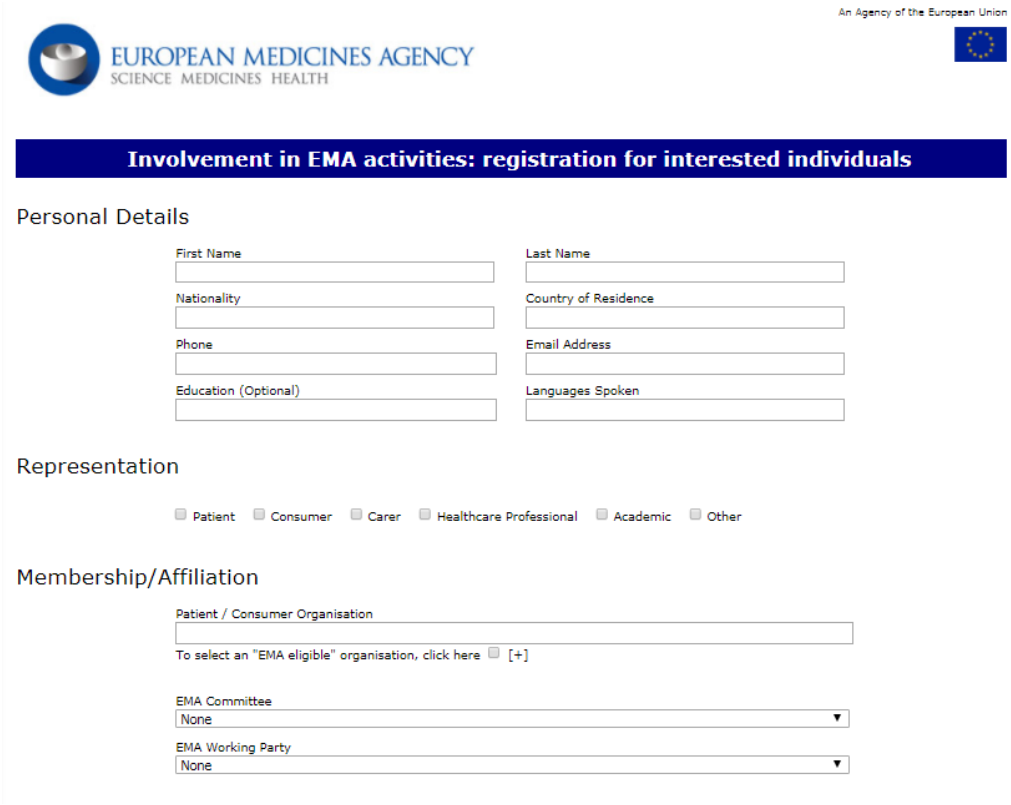
Learned societies/ healthcare professional organisations

Working Parties: Patients and Consumers (PCWP) and Healthcare Professionals (HCPWP)

- *Platform for dialogue and exchange with PCOs/ HCPOs on relevant issues concerning medicines for human use*
- *Balanced representation of **different types of PCOs / HCPOs***
- *Members of the PCWP/ HCPWP are **selected from the list of eligible organisations***
- *All Scientific Committees have a member in each WP*



Individuals – database



An Agency of the European Union

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SCIENCE MEDICINES HEALTH

Involvement in EMA activities: registration for interested individuals

Personal Details

First Name | Last Name

Nationality | Country of Residence

Phone | Email Address

Education (Optional) | Languages Spoken

Representation

Patient | Consumer | Carer | Healthcare Professional | Academic | Other

Membership/Affiliation

Patient / Consumer Organisation

To select an "EMA eligible" organisation, click here [+]

EMA Committee: None

EMA Working Party: None

EMA is reaching out to individual patients interested in getting involved in Agency activities or receiving information.

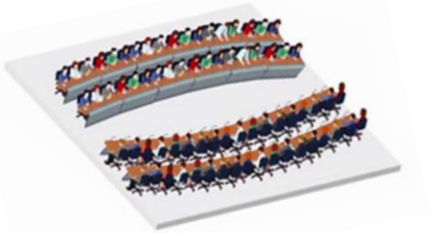
Registration is available via the website along with Question and Answer document.

Registration form enables individuals to highlight areas of interest.

How does EMA engage?

In writing

Conference calls



Committee meetings

Surveys

Face to Face

Preference Elicitation

Patients, Healthcare Professionals and Academia at EMA

What support and resources are available?

Annual training day

Webpages

Videos; EMA basics

Info-sheets

One-to-one personalised support

Information to stakeholders

It is important to provide targeted information to the right stakeholder group

Involve them in the review of the documents

Training resources also available:

- *Leaflets and information sheets*
- *Short videos explaining the role of EMA and its activities*

EMA Training Resources

EMA has developed a series of **training videos** targeted at patients and consumers entitled 'EMA basics'.

Together with the videos, EMA provides the presentation slides and related documents.

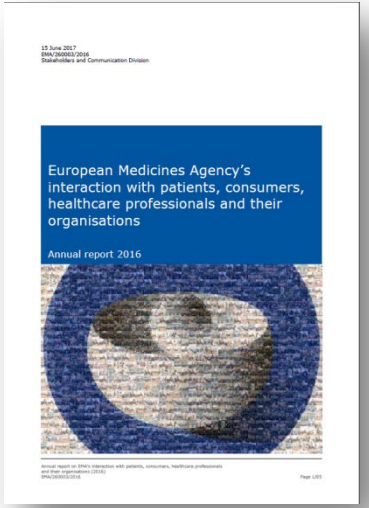
'EMA Basics' videos	Related documents
The European Medicines Agency	Presentation - The European Medicines Agency
The centralised procedure	Presentation - The centralised procedure
Involvement of patients	Presentation - Involvement of patients
The Patients' and Consumers' Working Party	Presentation - The Patients' and Consumers' Working Party
EMA video for patient representatives	Involvement of patient representatives in scientific advice procedures at EMA Involvement of patient representatives in scientific advisory groups at EMA
Pharmacovigilance	Presentation - Pharmacovigilance
How EMA works with healthcare professionals	Presentation - How EMA works with healthcare professionals

Transparency

- *Declarations of Interest – publication of declarations and CVs of individual experts*
- *Eligibility criteria for organisations and publication of funding*
- *Publication of agendas, minutes, highlights of committees*
- *Civil society members in committees*
- *Proactive publication of clinical trial data*
- *Public Hearing*

Monitoring and Reporting

- ***Activities*** *of stakeholders at EMA are monitored*
- ***Annual report*** *published on the interactions of EMA with patients, consumers, healthcare professionals and academics*
- *System is in place to constantly* ***measure satisfaction*** *and gather feedback for improvement*



Public Hearing

- *First public hearing*
- *September 26, 2017*
- *Valproate-containing medicines*
- *Engage with EU citizens including:*
  - *Patients*
  - *Healthcare professionals*
  - *Academia*
  - *Pharmaceutical companies*
  - *Press*

Patients, Healthcare Professionals and Academia at EMA

Take home messages

- ***Added value of engaging with stakeholders***
  - *Helps bridge the gap between regulatory and real world*
  - *Increases transparency leads to more trust*
  - *Involvement leads to more meaningful regulatory outcomes*
- ***Engage in a step by step approach;*** *learn together what format works best*
  - *Provide support – define roles - manage expectations – give feedback*
  - *Ensure engagement is mutually beneficial*
  - *Everyone benefits from knowledge sharing*
- *Citizens need to feel as though they are* ***part of the system*** *and understand and see value in interacting with the medicines agency.*

EMA Stakeholder engagement principles

Interactions with ***Industry Stakeholders***

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Scope of interaction – Who?

Industry stakeholders are organisations, associations and parties interacting with EMA which have interest in or are affected by the work of the Agency and its partners.

- *Interaction with industry "trade" associations*
- *NOT routine interaction with individual applicant companies*

Cover human & veterinary Pharmaceutical organisations

Associations of professionals operating in or supporting the industry

Associations of service providers to the industry

Pharmaceutical industry trade associations

Associations with multi-stakeholder membership including industry

Organisations engaged early on in the innovation life-cycle from development

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Framework for interaction between EMA and industry associations

Purpose

*Aims to **formalise** and **structure** our interaction with industry stakeholder groups.*

Scope

*Framework will **cover interaction** between Agency and industry associations.*

.

Implementation

***Monitoring** and **reporting** on the interaction.*

Key principles

- *Facilitate & **streamline** communication*
- ***Structured** interaction*
- ***Accountability***
- ***Transparency***
- ***Broad representation** of the industry*

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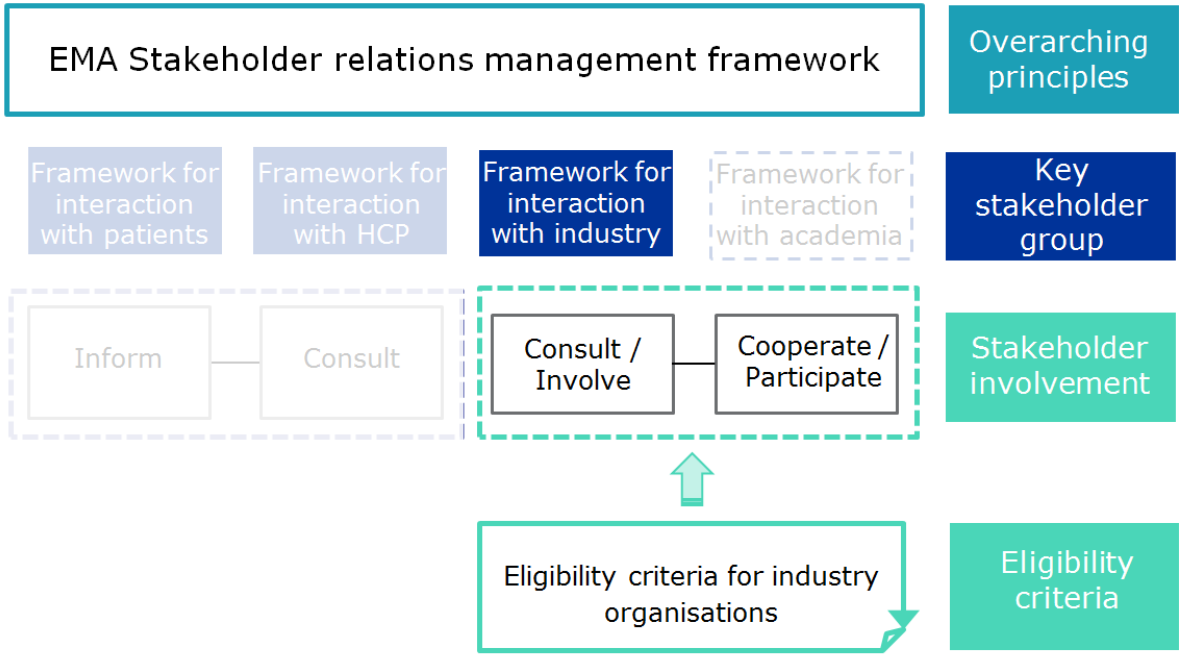
Eligibility criteria for industry

These criteria do not apply to the Agency procedure for external consultation on documents, since such consultation is open to all external parties.



- *Drawn up to ensure participating associations represent the broadest array of relevant pharmaceutical industry stakeholders.*
- *Designed taking into account the general principles for stakeholder consultation outlined in the European Commission's Better Regulation package.*

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Eligibility criteria for industry

- *Legitimacy: EU wide representation with interests of a specific constituency; a legal entity registered in one of the Member States of the EU/EEA; non-for-profit.*
- *Activities: Clear defined mission/objectives and a legitimate interest in the areas of work of the EMA; a specific interest in medicinal products for human or veterinary use.*
- *Entry in European Commission EU Transparency Register*
- *Representation: Representative of all its members/affiliations throughout the EU/EEA with processes in place supporting information flow.*
- *Structure: Governing bodies, which are elected by their members, where applicable.*

- *The names of eligible industry stakeholder organisations will be published on the EMA website.*
- *The implementation of these eligibility criteria will be monitored and may be subject to review as experience is gained.*

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Criteria to be fulfilled by industry stakeholder organisations involved in European Medicines Agency (EMA) activities

1. Introduction

Published list of Industry stakeholders organisations

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2017
EMA/26652/2017
Stakeholders and Communication

List of eligible industry stakeholder organisations

With reference to the Criteria to be fulfilled by industry stakeholder organisations involved in EMA activities, (EMA/323235/2016), the following organisations have been deemed eligible to be consulted and involved directly or to co-operate with the Agency in specific areas. All of the organisations in this list are also included in the EC Transparency Register, which provides further detailed information (link)

Name of organisation	Acronym	Website
Active Pharmaceutical Ingredients Committee	APIC	http://apic.cefic.org/
Association of Clinical Research Organizations	ACRO	www.acrohealth.org
Association of the European Self-Medication Industry	AESGP	www.aesgp.eu/
Association of Veterinary Consultants	AVC	www.avc.at/
European Association for Bioindustries	EuropaBio	www.europabio.org/
European Association for Logistics and Transportation in Healthcare	EALTH	www.ealth.org/
European Association of Euro-Pharmaceutical Companies	EAEPC	www.eaepc.org
European Biopharmaceutical Enterprises	EBE	www.ebe-biopharma.eu/
European Coalition on Homeopathic & Anthroposophic Medicinal Products	ECHAMP	www.echamp.eu/
European Confederation of Pharmaceutical Entrepreneurs	EUCOPE	www.eucope.org/
European Contract Research Organization Federation	EUCROF	www.eucrof.eu/
European Federation of Pharmaceutical Industries and Associations	EFPIA	www.efpia.eu/
European Federation of Statisticians in the Pharmaceutical Industry	EFSPI	www.efspi.org
European Group for Generic Veterinary Products	EGGVP	www.eggvp.org/
European Healthcare Distribution Association	GIRP	www.girp.eu/
European Industrial Pharmacists Group	EIPG	www.eipg.eu
Europharm SMC	Europharm SMC	www.europharmsmc.org/
Eye-Care Industries European Economic Interest Grouping	ECI-EEIG	www.eci-eeig.org
IFAH-Europe	IFAH-Europe	www.ifaheurope.org/
Medicines for Europe	N/A	www.medicinesforeurope.com/
Plasma Protein Therapeutics Association	PPTA	www.pptaglobal.org/
Vaccines Europe	VE	www.vaccineseurope.eu/

Disclaimer: It is the responsibility of each individual industry organisation to inform EMA with any changes which may affect their eligibility status as per the enclosed criteria (link) and information submitted when eligibility was granted.

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Industry Stakeholders interactions: Examples

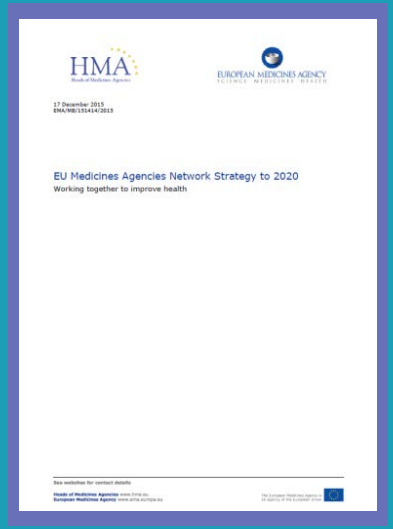
EUROPEAN MEDICINES AGENCY

Important topic-driven meetings and targeted consultation

*Industry **consultation** on:*

- *Operation of the **EU Medicines Regulatory Network** – EU Medicines Agencies Network strategy to 2020 – April 2015;*
- ***EU Telematics implementation**: WS on Common submission portal – April 2015 and consultation on draft EU telematics strategy and road map 2015-2017;*
- ***New transparency measures** to implement EU Clinical Trial Regulation & Agency's **policy on publication of clinical data** (policy0070) August 2015-December 2016;*
- *New scheme to reinforce support to human medicines for unmet medical needs (**PRIME**) October 2015*

EU medicines Agencies Network Strategy to 2020



Industry Stakeholders interactions: Examples

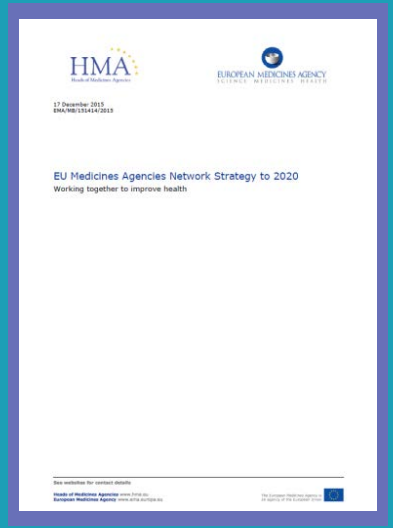
EUROPEAN MEDICINES AGENCY

Important topic-driven meetings and targeted consultation

- ***EMA-Industry Platforms meetings*** *to provide post-implementation* ***dialogue*** *on recent legislation, policies and initiatives with view in* ***optimising practical operational*** *aspects based on stakeholders experience:*
  - *Pharmacovigilance – Industry feedback on 2012 PhV implementation (11) Sept. 2014- Sept 2017;*
  - *Centralised evaluation (4) Apr. 2015- April 2017;*
  - *Research and development Support (1) April 2017;*

- ***Workshops on guideline /concept papers related development/ finalisation****:*
  - *Workshop on ICH Q3D from Quality perspective April 2015;*
  - *Challenges for Approval of Anti-Cancer Immunotherapeutic February 2016*
  - *First in human guideline update June 2017*

EU medicines Agencies Network Strategy to 2020


HMA

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17 December 2015
EMA/MB/151414/2015

EU Medicines Agencies Network Strategy to 2020
Working together to improve health

Any questions?

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Thank you for your attention

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Further information

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